I. Rejections under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 26 - 42 under 35 U.S.C. § 112, first paragraph, "*as based on a disclosure which is not enabling. Device limitations which are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure.*"

The Examiner alleged that "*the disclosure lacks any enablement for a claimed device other than the basic output port, actuator and chamber. No other device limitations are found in the application which would enable those of ordinary skill to make, use or practice the claimed device.*"

This rejection is respectfully traversed.

The pending independent claim reads as follows:

> 26. A device for delivering a medicament to a patient, comprising
> an output port defining a passage for dispensing controlled release particles of a cohesive composite of a medicament and a pharmaceutically acceptable carrier to a patient;
> a chamber containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter;
> an actuator coupled to the chamber, the actuator selectively causing the cohesive composite particles to be dispensed to the patient through the passage of the output port.

The Examiner is directed to pages 19 - 25 of the specification where particular medicament delivery devices are described. Examples of such devices include the Bespak device at page 20 line 24, page 21 line 15 and described in PCT publication WO 92/00771 (incorporated by reference), the Priestly device as described at page 21 lines 16 - 23 and in U.S. Patent No. 2,587,403 (incorporated by reference) and the Struve device as described at page 21 line 24, page 22 line 25 and in U.S. Patent No. 4,274,403 (incorporated by reference). The specification further discloses other devices on the above-cited pages. It is respectfully submitted that, at the very least, in view of this section of the specification, one of ordinary skill would be enabled to

make, use or practice the claimed device.

Further, the controlled release particles of the instantly claimed invention are disclosed in the specification at pages 26 - 30. Specific formulations and manufacturing procedures are set forth in the specific examples.

For the above reasons, it is respectfully submitted that the instant invention is adequately enabled by the description with respect to the device and the controlled release particles it stores and delivers. Therefore, the Examiner is requested to withdraw this rejection.

II. Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 26 - 42 under 35 U.S.C. § 112, second paragraph, "*as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.*"

The Examiner alleged that "[*t*]*he claims lack any device limitations which would particularly point out the claimed invention. Applicant is attempting to limit the device through the use of a claimed composition only. The claims are indefinite in that they do not distinctly claim a device.*"

This rejection is respectfully traversed.

Independent claim 26 of the instant invention recites a device with an output port defining a passage, a chamber containing cohesive composite particles and an actuator coupled to the chamber selectively causing the cohesive composite particles to be dispensed to the patient through the passage of the output port. This claim further provides for controlled release particles of a cohesive composite of a medicament and a pharmaceutically acceptable carrier containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter.

The claims are directed to a device with a particular formulation contained therein. Specifically, the claims recite a device containing an output port, a chamber and an actuator

coupled to the chamber, and pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, it is submitted that the Examiner has not alleged that any of these elements are unclear. Rather, the Examiner appears to object to the broadness of the claims. This is not a proper basis for a rejection under 35 U.S.C. § 112, second paragraph. Withdrawal of the Examiner's rejection is therefore respectfully requested.

III. Rejections under 35 U.S.C. § 102(b)

The Examiner also rejected claims 26 - 42 under 35 U.S.C. § 102(b) "as being clearly anticipated by Burns, et al." (The Burns Patent).

According to the Examiner, the Evans patent "*disclose[s] a device for delivering medicament to a patient comprising an output port, a chamber, and an actuator which propels the medicament through the output port.*" The Examiner further states that "*[t]he method of treating a patient by inhalation is disclosed*" and "*[c]omposition limitations can not be used to define the claimed device over that of the prior art.*" The Examiner provides no legal authority in support of the position that composition limitations may not be used in claiming a device.

This rejection is respectfully traversed.

It is respectfully submitted that a proper rejection under 35 U.S.C. § 102(b) requires that each and every limitation of a claim be found in a prior art reference. See Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 U.S.P.Q.2D 1508, 1512 (Fed. Cir. 2001), In re Bond. 910 F. 2d 831, 832 (Fed.Cir. 1990); Lindeman Machinefabrik v. Am Hoist and Derrick. 730 F. 2d 1452, 1458 (Fed. Cir. 1984). The Evans patent fails to teach hint or suggest the use of a pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum as claimed in independent claim 26 of the instant invention.

Applicants note that numerous claims have issued which recite a novel pharmaceutical formulation in a prior art carrier. In the chemical arts, this scenario can readily be illustrated by a novel dosage form that contains a claim element directed to a novel formulation contained within a prior art gelatin capsule. Applying the Examiner's reasoning to this example:

> *A formulation stored and administered in a known capsule cannot be used to define the dosage form. Therefore, the dosage form, containing a novel*

formulation and a known gelatin capsule would be unpatentable.

Clearly, this reasoning provides a result that is incorrect. When determining patentability, it would be incorrect to ignore claim limitations directed to the formulation simply because the carrier capsule is not novel.

Moreover, courts have repeatedly held that a single novel feature added to a known combination is patentable. The decisions in Radio Steel and In re Bernhart rejected the holding in Lincoln Engineering Co. v. Stewart, 303 U.S. 545 (1938), which held that "*the improvement of one part of an old combination gives no right to claim that improvement in combination with other old parts which perform no new function in the combination*" as untenable under the current patent laws. Radio Steel & Mfg. Co. v. MTD Products, Inc., 731 F.2d 840, (Fed. Cir. 1984) at 845; In re Bernhart, 417 F. 2d. 1395, (1969) at 1403; See also M.P.E.P. at § 2173.05(j).

As noted above, a claim must be analyzed in its entirety. For example, the Diehr Court held *"[a] prior art machine that used a new mathematical algorithm is a new machine or at least a useful improvement of a machine that is clearly patentable subject matter."* 450 U.S. 181 (1981) at 187. In so holding, the Court advised that consideration of the invention must include all the claim limitations, taken as a whole. Id., at 187.

It is submitted that the reasoning applied in repealing the point of novelty principle under 35 U.S.C. § 101 is equally applicable to other statutory requirements, including 35 U.S.C. § 102. As the Diehr Court explained, all claim limitations of a machine, even including elements that are not, in and of themselves patentable subject matter, must be considered for patentability. This rationale is also discussed in In re Bernhart, which held with respect to the computer arts, "[i]*f the prior art does not show or suggest the improved element itself, it defies logical reasoning to say that the same prior art suggests the use of that improved element in a combination.*" In re Bernhart, 417 F. 2d. 1395, (1969) at 1402. Moreover, this reasoning is not peculiar to mathematical algorithms or software, but applies to any device. For example, in Radio Steel, the court applied the reasoning of In re Bernhart in assessing the novelty of a wheelbarrow, in rejecting Lincoln Engineering. Radio Steel v. MTD, 731 F.2d at 845.

The presently claimed invention is also a novel formulation (containing xanthan gum and

locust bean gum) stored in and administered with a known carrier device. Applying the above reasoning and considering all the claim limitations as a whole, it must be determined that the invention is novel. Therefore, it is believed that the Examiner's rejection of claims 26-42 is improper, and should be withdrawn.

The Examiner alleged that the Burns patent " disclose[s] a device which comprises an output port, an actuator and a chamber." The Examiner further states that "[t]he method of delivery is disclosed" and "[c]omposition limitations can not be used to define the claimed device over that of the prior art."

This rejection is respectfully traversed.

As discussed above, with respect to the Evans patent, the Burns patent also does not recite limitations directed to a carrier formulation comprising xanthan gum and locust bean gum. Therefore, it is respectfully requested that the Examiner's rejection be withdrawn.

IV. Conclusion

In view of the actions taken and arguments presented, it is respectfully submitted that this application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at the telephone number provided below if it is determined that any further issues remain.

Respectfully submitted,
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By: _____

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